IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INDIVIOR INC., and INDIVIOR UK LIMITED, Plaintiffs, v. PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES INC., and ENDO INTERNATIONAL PLC, Defendant.	Civil Action No. _____

I. COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior") and Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK"), (collectively, "Plaintiffs") file this Complaint against Defendants Par Pharmaceutical, Inc. ("Par Pharmaceutical"), Par Pharmaceutical Companies Inc. ("Par Pharmaceutical Cos.") and Endo International PLC ("Endo") (collectively "Par" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Par's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiffs' Suboxone® sublingual film prior to the expiration of United States Patent No. 9,687,454 ("the '454 patent" or "the patent-in-suit").

THE PARTIES

2. Plaintiff Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff Indivior UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. On information and belief, Defendant Par Pharmaceutical is a corporation organized and existing under the laws of New York, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

5. On information and belief, Par Pharmaceutical is a wholly-owned subsidiary of Par Pharmaceutical Cos.

6. On information and belief, Par Pharmaceutical is a wholly-owned subsidiary, directly or indirectly, of Endo and holds itself out as "an Endo International Company."

7. On information and belief, Defendant Par Pharmaceutical Cos. is a corporation organized and existing under the laws of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

8. On information and belief, Defendant Par Pharmaceutical Cos. is a holding company.

9. On information and belief, Defendant Par Pharmaceutical Cos. is a wholly-owned subsidiary, directly or indirectly, of Endo.

10. On information and belief, Defendant Endo International PLC is a publicly-traded company organized and existing under the laws of Ireland, having a place of business at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

11. On information and belief, Defendant Endo has a regular and established place of business within this judicial district in Cranbury, New Jersey.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Par Pharmaceutical because of, *inter alia*, Par Pharmaceutical's continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of this judicial district, and its substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

14. This Court has personal jurisdiction over Par Pharmaceutical Cos. because of, *inter alia*, its continuous and systematic contacts with the State of New Jersey and corporate entities within this judicial district, including its subsidiary, agent, and/or alter-ego, Par Pharmaceutical, a company registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler, its previous submission to the jurisdiction of this judicial district, and its substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district including through, directly or indirectly, Par Pharmaceutical.

15. This Court has personal jurisdiction over Endo because of, *inter alia*, Endo's continuous and systematic contacts with corporate entities within this judicial district, and Endo's marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

16. On information and belief, Par Pharmaceutical is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval for, marketing, selling, and

distributing pharmaceutical products, including generic copies of branded pharmaceuticals, in New Jersey and throughout the United States.

17. On information and belief, Par Pharmaceutical directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this judicial district.

18. Upon information and belief, Par Pharmaceutical is registered with the State of New Jersey's Department of Health as a "Manufacturer and Wholesale[r]," registration number 5004032.

19. On information and belief, Par Pharmaceutical has availed itself of the jurisdiction of this Court by previously filing lawsuits in this judicial district. *See*, *e.g.*, *Par Pharm., Inc. et al. v. Luitpold Pharms., Inc.*, No. 16-01190 (D.N.J.); *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, No. 13-04000 (D.N.J.).

20. On information and belief, Par Pharmaceutical and Par Pharmaceutical Cos. have previously been sued in this judicial district and have not challenged personal jurisdiction and venue. *See, e.g.*, *Horizon Therapeutics, LLC v. Par Pharmaceutical, Inc.*, No. 17-05901 (D.N.J.); *Celgene Corp. v. Par Pharmaceutical Inc.*, No. 17-03159 (D.N.J.); *Alcon Labs., Inc. v. Dr. Reddy's Labs.*, No. 16-06775 (D.N.J.); *BioMarin Pharmaceutical Inc. v. Par Pharmaceutical Inc.*, No. 16-01015 (D.N.J.); *Jazz Pharms., Inc. v. Par Pharm., Inc.*, No. 15-7580 (D.N.J.); *Shire LLC v. Par Pharm., Inc.*, No. 15-01454 (D.N.J.); *Supernus Pharms., Inc. v. Par Pharm. Cos., Inc.*, No. 15-00326 (D.N.J.).

21. On information and belief, Par Pharmaceutical and Par Pharmaceutical Cos. have further availed themselves of the jurisdiction of this Court by filing counterclaims in this judicial district. *See*, *e.g.*, *Horizon Therapeutics, LLC v. Par Pharmaceutical, Inc.*, No. 17-05901

(D.N.J.); *Alcon Laboratories, Inc. v. Dr. Reddy's Laboratories Ltd. et al.*, No. 16-06775 (D.N.J.); *West-Ward Pharmaceuticals Corp. v. Par Pharmaceuticals Inc.*, No. 16-05456 (D.N.J.); *Horizon Therapeutics, LLC v. Par Pharmaceutical Inc.*, No. 16-03910 (D.N.J.); *Merck Sharp & Dohme Corp. v. Par Sterile Products, LLC*, No. 16-00948 (D.N.J.); *BioMarin Pharmaceutical Inc. v. Par Pharmaceutical Inc.*, No. 16-01015 (D.N.J.); *Fresenius Kabi USA, LLC v. Fera Pharmaceuticals, LLC*, No. 15-03654 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical Inc.*, No. 15-07580 (D.N.J.); *BioMarin Pharmaceutical Inc. et al. v. Par Pharmaceutical Inc.*, No. 15-01706 (D.N.J.); *Alcon Pharmaceuticals Ltd. v. Par Pharmaceutical Inc.*, No. 15-07240 (D.N.J.); *Fresenius Kabi USA, LLC v. Par Sterile Products, LLC*, No. 15-03852 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 15-03217 (D.N.J.); *Helsinn Healthcare S.A. v. Par Pharmaceutical Companies Inc.*, No. 15-02078 (D.N.J.); *Shire LLC v. Par Pharmaceutical Inc.*, No. 15-01454 (D.N.J.);; *Supernus Pharmaceuticals, Inc. v. Par Pharmaceutical Companies, Inc.*, No. 15-00326 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical Inc.*, No. 15-00173 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, No. 14-06150 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, No. 14-05139 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, No. 13-07884 (D.N.J.); *Purdue Pharmaceutical Products L.P. v. Par Pharmaceutical, Inc.*, No. 12-06738 (D.N.J.); *Depomed, Inc. v. Impax Laboratories, Inc.*, No. 12-02154 (D.N.J.).

22. On information and belief, Endo acquired Par Pharmaceutical Holdings, Inc. on September 25, 2015. Endo's 2015 Form 10-K states, "Immediately following the closing, Par Pharmaceutical Holdings, Inc. changed its name to Par Pharmaceutical Companies, Inc. (Par)." *See* Endo 2015 Form 10-K at 3, https://www.sec.gov/Archives/edgar/data/1593034/000159303415000005/endp-

12312014x10k.htm (last visited October 6, 2017). Endo's 2015 Form 10-K also states that "Par has operated in two business segments, (i) Par Pharmaceutical, which includes generic products … and (ii) Par Specialty Pharmaceuticals, which markets three branded products." *Id.*

23. On information and belief, Par Pharmaceutical holds itself out as "an Endo International Company." In the Paragraph IV Notice Letter Par Pharmaceutical sent to Plaintiffs regarding the '454 patent, Par Pharmaceutical identified itself as a "Endo International Company."

24. On information and belief, Endo holds out to the public that it has a physical location in Cranbury, New Jersey. *See, e.g.*, http://www.endo.com/about-us/locations (last visited October 6, 2017).

25. On information and belief, Endo operates and maintains a regular and established place of business located at 7 Clarke Drive, Cranbury, New Jersey 08512. *See, e.g.*, http://www.endo.com/about-us/locations (last visited October 6, 2017).

26. On information and belief, Endo lists a Research and Development property, located in Cranbury, New Jersey, as part of its "U.S. Generic Pharmaceuticals Segment" on its most recent Form 10-K filed on March 1, 2017. *See* Endo 2017 Form 10-K at 43, https://www.sec.gov/Archives/edgar/data/1593034/000159303417000009/endp-12312016x10k.htm (last visited October 6, 2017).

27. On information and belief, Par Pharmaceutical and Par Pharmaceutical Cos. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

28. On information and belief, Par Pharmaceutical acts at the direction, and for the benefit, of Par Pharmaceutical Cos. and Endo, and is controlled and/or dominated by Par Pharmaceutical Cos. and Endo.

29. On information and belief, Endo, either directly or indirectly through its wholly-owned subsidiaries, is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in New Jersey and throughout the United States.

30. On information and belief, Par Pharmaceutical, Par Pharmaceutical Cos., and Endo hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic pharmaceutical products in the United States.

31. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

32. Plaintiff Indivior UK is the lawful owner of the '454 patent, and Plaintiff Indivior is an exclusive licensee of the '454 patent. The '454 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on June 27, 2017, naming Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, Beuford Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the '454 patent is attached hereto as Exhibit A.

SUBOXONE® SUBLINGUAL FILM

33. Plaintiff Indivior is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

34. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the treatment of opioid dependence. Plaintiff Indivior has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

35. The '454 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Suboxone® sublingual film.

THE DRUG APPROVAL PROCESS

36. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that innovator drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

37. Under 21 U.S.C. § 355(b)(1), the innovator drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in the Orange Book.

38. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDAs can rely on FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-approved drug.

39. When a generic manufacturer submits an ANDA, the FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. See 21 C.F.R. § 314.101(b)(1). "Receipt of an [ANDA] means that FDA has made a threshold

determination that the abbreviated application is sufficiently complete to permit a substantive review." Id.

40. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date, and the generic will stay off the market until that date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV" certifications).

41. If the ANDA includes a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice to the patent owner of the factual and legal basis for the applicant's opinion that patents listed in the Orange Book are invalid or will not be infringed ("Notification Letter"), "not later than 20 days after the date of the postmark on the notice with which the [FDA] informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B).

42. If the patent owner files an infringement action within 45 days of receiving the Notification Letter, a 30-month injunction or stay of the FDA approval is triggered, calculated from the date of receipt of the Notification Letter. See 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

PAR'S PARAGRAPH IV NOTICE

43. Plaintiffs received the Notification Letter from Par. In the Notification Letter, Par identified itself as a "Endo International company." The Notification Letter from Par, dated August 7, 2017, states that ANDA No. 205854 contains Paragraph IV certifications alleging that the '454 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

44. The Notification Letter further states that Par submitted ANDA No. 205854 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of Par's generic product before expiration of the patent-in-suit. On information and belief, ANDA No. 205854 concerns dosages of Par's generic product and refers to and relies on Plaintiff Indivior's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Par's generic product with Suboxone® sublingual film.

COUNT 1
Infringement of the '454 Patent Under 35 U.S.C. § 271(e)(2)

45. On information and belief, Defendants' generic product is covered by one or more claims of the '454 patent.

46. By filing ANDA No. 205854 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Defendants' generic product prior to the expiration of the '454 patent, Defendants have committed an act of infringement of the '454 patent under 35 U.S.C. § 271(e)(2).

47. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter alia, an order of this Court that the FDA set the effective date of approval for ANDA No. 205854 to be a date which is not any earlier than the expiration date of the '454 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Defendants have infringed the '454 patent under 35 U.S.C. § 271(e)(2) by submitting and maintaining ANDA No. 205854;

B. A declaratory judgment that Defendants' commercial manufacture within the United States of Defendants' generic product would infringe the '454 patent under 35 U.S.C. § 271;

C. Preliminary and permanent injunctions, restraining and enjoining Defendants, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patent-in-suit;

D. An order that the effective date of any approval of ANDA No. 205854 be a date that is not earlier than the expiration of the patent-in-suit, including any extensions thereof and any later expiration of exclusivity associated with the '454 patent;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendants commercially manufacture, use, offer to sell, or sell in the United States, or import into the United States, Defendants' generic product before the expiration of the patent-in-suit, including any extensions; and

G. Any and all other relief as the Court deems just and proper.

Dated: October 6, 2017 **TROUTMAN SANDERS LLP**

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